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FACSIMILE TRANSMITTAL

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OCT 1 2 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Goren et.al.

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SERIAL NO: 09/827,493

FILED: -04/06/01

O1/14/2602

FOR: ANTIVIRAL COMPOSITION DERIVED
FROM ALLIUM CEPA AND
THERAPEUTIC USE THEREOF

SEXAMINER: HOFFMAN, SC

S GROUP ART UNIT: 1655

DOCKET: P 0280702/

9 03013/01D1

S71-273-8300 CERTIFICATION OF FACSIMILE TRANSMISSION

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BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is the Diepon S.A., the assignee of the entire interest in the above application via assignment recorded at reel/frame location011113/0324.

(2) Related Appeals and Interferences

There are no other appeals or interferences known to appellant, the appellant's legal representative or the assignee which will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

(3) Status of Claims

This appeal is from the final rejection of all pending claims dated 13 November 2006 and an Advisory Action maintaining the Final Rejection dated 9 March 2007.

(4) Status of Amendments

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(A) Claims 8-10 and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) for the reasons set forth in the previous Office action.

The Examiner contends as follows:

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach using onion in the amounts claimed by applicant. However, the reference teaches only specifically mentions onion as one active ingredient in the method to treat the common cold. The reference does not specifically teach the percentage of onion included in the compositions. However, the dosage of a specific ingredient is well known in the art to be a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount dosage of onion to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

(B) Claims 8-10, 12, 13, 39-40 and 43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) in view of US Pat. No. 4,409,237 for the reasons set forth in the previous Office action.

The Examiner contends as follows:

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that CN '152 teaches away from using a high dosage of onion in the composition based on the "significant amount" of other material included in the composition of CN '152. However, CN '152 is not considered by the examiner to require a "significant amount" of material other than the onion. The reference teaches only one active ingredient, onion, and states that this can be administered in various pharmaceutical forms. No other ingredients are specifically required. Thus, CN '152 is not considered to teach away from using a high dosage of onion. Therefore, the claims are considered properly rejected for the reasons of record.

13 November 2006 Final Office Action.

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(5) Summary of Invention

The present invention relates to pharmaceutical compositions and oral medications including a particulate, dehydrated plant material derived from a species of Allium selected from the group consisting of Allium cepa, Allium ampeloprasum, Allium fistulosa, and Allium schoenoprasum having particles ranging in size from about 1 to 1,400 microns and having a water content of less than or equal to 5.5% and where the effective amount is between 5 and 50 grams per day. The particulate, dehydrated plant material is derived directly from the species of Allium after processing to clean the raw plant, dehydrate the raw plant and commutate the dehydrated raw plant to particles of a size between 1 and 1,400 microns. The material is not further processed.

(6) Issues

- (A) Whether the inventions encompassed by Claims 8-10 and 12 are unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) for the reasons set forth in the previous Office action
- (B) Whether the inventions encompassed by claims 8-10, 12, 13, 39-40 and 43 are unpatentable over Chinese Pat. Appl. No. 1089152 A (1994) in view of US Pat. No. 4,409,237.

(7) Grouping of Claims

Claims 8-10, 12-13, 39-40 and 43 relate to pharmaceutical compositions for treating viral infections including a particulate, dehydrated plant material derived from a species of Allium selected from the group consisting of Allium cepa, Allium ampeloprasum, Allium fistulosa, and Allium schoenoprasum having particles ranging in size from about 1 to 1,400 microns and having a water content of less than or equal to 5.5% and where the effective amount is between 5 and 50 grams per day.

(8) Argument

(A) Applicants assert that this invention is non-obvious over the cited prior art because the prior art does not disclose, teach or even suggest "a particulate, dehydrated plant material" as

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required in the claims of this application over Chinese Pat. Appl. No. 1089152 A (1994).

During the last stage of examination, Applicants pointed out a discrepancy between the Examiner's Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) and the EPO English abstract of Chinese Pat. Appl. No. 1089152 A (1994). The EPO abstract disclosed that the Chinese Pat. Appl. No. 1089152 A (1994) composition was formed from a liquid derived from onion by extraction and distillation. The Examiner then requested a full translation of Chinese Pat. Appl. No. 1089152 A (1994), which was forwarded to Applicant. The full translation is in agreement with the EPO abstract and not the Derwent English abstract. The Chinese Pat. Appl. No. 1089152 A (1994) makes it clear that their composition contains an onion juice prepared "from onion by means of pressing, concentrated, dried, ground, and developed into the powder preparation . . . " Chinese Pat. Appl. No. 1089152 A (1994) at claim 2. Thus, Chinese Pat. Appl. No. 1089152 A (1994) does not disclose, teach or even suggest a particulate, dehydrated patent material, but discloses a herbal medicament prepared using a juice derived "from onion by means of pressing, concentrated, dried, ground, and developed into the powder preparation . . . " Chinese Pat. Appl. No. 1089152 A (1994) at claim 2. The Chinese Pat. Appl. No. 1089152 A (1994) composition clearly is not a particulate. dehydrated plant material; it is a juice of a plant material that is highly processed and later dewatered to form a powdered material.

Because Chinese Pat. Appl. No. 1089152 A (1994) does not disclose, teach or even suggest a method of administering a particulate, dehydrated plant material composition, but only a method of administering an extracted and distilled composition irrespective of its final form, Chinese Pat. Appl. No. 1089152 A (1994) does render the pending claims of this invention obvious. Applicants, therefore, respectfully request a reversal of the Examiner's 103(a) rejection.

(B) Applicants repeat their arguments relating to Chinese Pat. Appl. No. 1089152 A (1994) as set forth above. While US Pat. No. 4,409,237 discloses powders and humidity and Chinese Pat. Appl. No. 1089152 A (1994) discloses compositions that can be in the form of a powder, Chinese Pat. Appl. No. 1089152 A (1994) is not a method of administering a composition comprising a particulate, dehydrated plant material as is true in the present claims. As stated above, the Chinese

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Pat. Appl. No. 1089152 A (1994) composition contains a juice prepared "from onion by means of pressing, concentrated, dried, ground, and developed into the powder preparation..." Chinese Pat. Appl. No. 1089152 A (1994) at claim 2.

The combination of Chinese Pat. Appl. No. 1089152 A (1994) and US Pat. No. 4,409,237 does nothing to remove the deficiencies of Chinese Pat. Appl. No. 1089152 A (1994) as it relates to the nature of the composition being administered – a composition comprising a particulate, dehydrated plant material – not a composition derived from squeezing, solvent extracting and distilling.

Because the combination of Chinese Pat. Appl. No. 1089152 A (1994) and US Pat. No. 4,409,237 does not disclose, teach or even suggest a method of administering a particulate, dehydrated plant material composition, but only a method of administering a powdered composition containing a juice prepared "from onion by means of pressing, concentrated, dried, ground, and developed into the powder preparation . . ." (Chinese Pat. Appl. No. 1089152 A (1994) at claim 2), the combination does render the pending claims of this invention obvious. Applicants, therefore, respectfully request reversal of the Examiner's 103(a) rejection.

If additional information or communications are needed during the pendency of this Appeal, the Patent Office can contact Applicant's attorney at 713.977.7000 or by email at rwstroz@flash.net.

Date: October 12, 2007

Robert W. Strozier Registration No. 34,024

Respectfully submitted

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(9) Appendix - Copy of Claims involved in this Appeal

This appeal is from the final rejection of claims 1-32 and 46-48. Claims 33-45 were withdrawn and relate to a non-elected group and are not at issue here. Claims 1-32 and 46-48 read as follows:

- l.(withdrawn)
- 2.(withdrawn)
- 3.(withdrawn)
- 4.(withdrawn)
- 5.(withdrawn)
- 6.(withdrawn)
- 7.(withdrawn)
- 1 8.(previously presented) A method for treating a viral infection in a patient comprising
- administering a therapeutically effective amount of a composition comprising a particulate,
- dehydrated plant material derived from a species of Allium selected from the group consisting of
- 4 Allium cepa, Allium ampeloprasum, Allium fistulosa, and Allium schoenoprasum having particles
- 5 ranging in size from about 1 to 1,400 microns and having a water content of less than or equal to
- 5.5% and where the effective amount is between 5 and 50 grams per day.
- 1 9.(previously presented) The method of claim 8, wherein the administering is orally
- 2 administering.
- 1 10.(previously presented) The method of claim 8, wherein the viral infection is selected from
- 2 the group consisting of influenza, herpes, hepatitis, parvovirus, distemper, RSV, CMV, rhinovirus,
- 3 rhabdovirus, papillomavirus, Epstein Barr, and foot and mouth disease virus.
- 1 11.(withdrawn) The method of claim 8, wherein the Allium species is Allium ampeloprasum.
- 1 12.(previously presented) The method of claim 8, wherein the Allium species is Allium cepa.

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- 1 13.(previously presented) The method of claim 8, wherein the particles have a particle size distribution comprising about 42.9% of particles having a size less than 250 microns, 56.9% of particles having a size less than 355 microns, and 74.7% of particles having a size less than 500
- 4 microns.
 - 14.(withdrawn)
 - 15.(withdrawn)
 - 16.(withdrawn)
 - 17.(withdrawn)
 - 18.(withdrawn)
 - 19.(withdrawn)
 - 20.(withdrawn)
 - 21.(withdrawn)
 - 22.(withdrawn)
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 - 27.(withdrawn) 28.(withdrawn)
 - 29.(withdrawn)
 - 30.(withdrawn)
 - 31.(withdrawn)
 - 32.(withdrawn)
 - 33.(withdrawn)
 - 34.(withdrawn)
 - 35.(withdrawn)
 - 36.(withdrawn)
 - 37.(withdrawn)
 - 38.(withdrawn)
- 1 39.(previously presented) The method of claim 8, wherein 64.6% of the particles have a particle
- 2 size of between 10 microns to 850 microns.
- 1 40.(previously presented) The method of claim 8, wherein 74.7% of the particles have a particle
- 2 size less than 500 microns.

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- 1 41.(withdrawn)
- 2 42.(withdrawn)
- 1 43.(currently amended) The method of claim 8, wherein 21.7% of the particles have a size
- ranging between 500-850 microns, 22.1% of the particles have a size ranging from 106-250 microns, 2
- 6.8% of the particles have a size ranging from 75-106 microns, 10.8% of the particles have a size 3
- 4 ranging from 36-75 microns, and 3.2% of the particles have a size less than 36 microns.

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